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IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF ORANGE,

CENTRAL JUSTICE CENTER

THE PEOPLE OF THE STATE OF CALIFORNIA, Plaintiff, vs. DV BIOLOGICS, LLC; DAVINCI BIOSCIENCES, LLC; ANDRES ISAIAS; ESTEFANO ISAIAS, SR; ESTEFANO ISAIAS, JR and DOES 1-10 Defendants	Case No.: **CIVIL COMPLAINT FOR VIOLATIONS OF BUSINESS AND PROFESSIONS CODE SECTION 17200 (UNLAWFUL, UNFAIR AND FRAUDULENT BUSINESS PRACTICES)** *Filing Fees Exempt (Govt. Code § 6103)*

The People of the State of California, by and through Tony Rackauckas, District Attorney for the County of Orange, hereby allege as follows:

INTRODUCTION

1. DV Biologics, LLC and DaVinci Biosciences, LLC obtained aborted fetus donations from Planned Parenthood and turned those donations into a profit-driven business. They did so by selling tissues and stem cells from the heart, lungs, kidneys, brain, intestines, skeletal muscle and bones of the aborted fetus donations. The companies advertised and sold

these "prenatal products" from 2009-2015 to companies all around the world, earning hundreds of thousands of dollars in revenue.

2. Although donations are permitted, the sale of fetal tissue and cells for "valuable consideration" is illegal under both California and federal law. (Cal. Health & Safety Code § 125320; 42 U.S.C. § 289g-2.) These laws were adopted to address the "significant ethical and policy concerns" that arose with the legalization of stem cell research and "to ensure that researchers have the tools necessary to fulfill the promise of stem cell research" -- an objective that cannot be achieved if stems cells are too expensive for the scientific community to acquire for research purposes. (Stats 2002, ch. 789 [S.B. No. 253] § 1 (g)-(h).)

3. Nonetheless, Defendants pressed onward, year-after-year, in an attempt to beat their "competition" and increase margins -- just as any profit-seeking enterprise may otherwise attempt to do. Indeed, rather than limiting their income on these sales, the companies intentionally set their prices as high as possible in an effort to maximize their profits. Sales and marketing staff were hired, paid commissions, and pressured to "push" sales in order to meet increasing revenue objectives every year. They were encouraged to offer discounts, coupons, and sales-pricing on fetal "products" to move "inventory" more quickly as well.

4. The business was lucrative. To be sure, fetal stem cell "products" were routinely sold at a 10-fold, or higher, mark-up over the minimal costs that were required to handle, process and distribute these "products" for sale. The company also charged packaging and handling fees, as well as marked-up shipping fees, so as to earn a little extra profit on every transaction.

5. It is estimated that the companies sold hundreds of different fetal tissue and stem cell "products" for valuable consideration in violation of the law. Each unlawful sale is a separate act of unlawful and unfair competition under California's Business and Professions Code Section 17200 for which civil penalties and injunctive relief are warranted and hereby sought by way of this Complaint.

JURISDICTION AND VENUE

6. At the relevant time period in this case, Defendants transacted business, employed workers and/or controlled a place of business in the County of Orange, in the state of California.

The unlawful conduct -- involving the unlawful sale of fetal tissue for valuable consideration -- occurred in the County of Orange, in the state of California at the Defendants' place of business.

7. Jurisdiction and venue are proper in this Court pursuant to California Code of Civil Procedure Sections 395 and 395.5 because the conduct giving rise to liability occurred in the County of Orange at the Defendants' places of business located at 1239 Victoria Street, Costa Mesa and 2667 Old Canal Road in Yorba Linda.

PARTIES

8. Tony Rackauckas, as District Attorney for the County of Orange, acting to protect the public from unlawful, unfair, or fraudulent business practices, brings this action in the public interest on behalf of the People. As such, the Plaintiff in this action includes the People of the State of California and the County of Orange (hereinafter, the "Plaintiff" or the "People").

9. Incorporated in November 2007, Defendant DaVinci Biosciences, LLC, is a Delaware Limited Liability Company with its principal place of business, as of June 24, 2015, located at 22667 Old Canal Road in Yorba Linda, in the County of Orange. Prior to June 2015, the principal place of business for DaVinci Biosciences was located at 1239 Victoria Street, Costa Mesa, in the County of Orange. The company filed an application for registration with the California Secretary of State in 2007; however, the California Franchise Tax Board forfeited the entity's powers, rights and privileges on July 28, 2015 and the entity's powers, rights and privileges have remained forfeited ever since.

10. Defendant DV Biologics, LLC was incorporated in Delaware on March 3, 2009, and shares its principal place of business, as of June 24, 2015, with DaVinci Biosciences, located at 22667 Old Canal Road in Yorba Linda, in the County of Orange. Prior to June 2015, the principal place of business for both companies was located at 1239 Victoria Street, Costa Mesa, in the County of Orange. The company filed an application for registration with the California Secretary of State in 2009; however, the California Franchise Tax Board forfeited the entity's powers, rights and privileges on November 3, 2014 and the entity's powers, rights and privileges have remained forfeited ever since.

11. DaVinci Biosciences is jointly owned and managed by Andres Isaias, Luis Isaias and Estefano Isaias. Andres Isaias, Luis Isaias, and Estefano Isaias also own and manage DV Biologics. The two companies share the same office space, employees, and management. The organization charts of both companies, demonstrating the unity of ownership, management and employees, in 2015 is attached hereto as **Exhibit A**. There is no separate accounting of the financials of the two companies; the accounting of revenue and expenses for both companies is 100% commingled. There is thus a unity of ownership and sharing of management, operations, revenues and expenses between the two companies such that there is little to no separation between the two. The two companies are alter egos of one another and are collectively referred to herein as "DV" or "Defendants."

12. Since 2012, the two companies also share office space, employees and operations with a third company called "TheBioBox LLC." TheBioBox LLC is a Delaware Limited Liability Company incorporated in 2012 which is doing business in California as a stem cell bank and laboratory. Defendant Andres Isaias is the President of TheBioBox. Andres Isaias applied to register TheBioBox as a foreign Limited Liability Company in the state of California in November 2012; however, the California Franchise Tax Board forfeited the entity's powers, rights and privileges on August 1, 2016 and the entity's powers, rights and privileges have remained forfeited ever since.

13. Defendant Andres Isaias is one of the founding members of the DV Defendants. In January 2011, he became the President of both companies and at all relevant time periods thereafter, he was the officer and manager in control of the business operations and activities of the DV Defendants. Andres Isaias, along with the other family members, managed and controlled the financial decisions, books and records for the DV companies from the time they were formed until the present date. Andres Isaias exercised control over the DV companies and directly participated in their operations by attending several business strategy and sales meetings at the California DV headquarters, facilitating an audit of the value of DV's inventory, and by requiring regular financial and other reports from DV employees from approximately 2009 to the

present date. Andres Isaias filed and signed, as President, the most recent Statement of Information for both DV Defendants with the California Secretary of State on January 31, 2011.

14. Defendants Estefano Isaias, Sr. and Estefano Isaias Jr., are father and son. Both Estefano Isaias, Jr. and Estefano Isaias, Sr. participated in the founding of the DV Defendants with Andres Isaias, who is the brother of Estefano Isaias Jr. and also the son of Estefano Isaias Sr. In January 2011, "Estefano Isaias" was designated as a manager and/or member of both companies and at all relevant time periods thereafter, has been one of the official managing members of the companies in control of the business operations and activities of the DV employees. Estefano Isaias, Jr., and Estefano Isaias, Sr, along with other family members, managed and controlled the financial decisions, books and records for the DV companies from the time they were formed until the present date. Both Estefano Isaias Jr., and Estefano Isaias Sr, exercised control over the DV companies and directly participated in their operations by working in concert with Andres Isaias to manage the companies, by attending several business strategy and sales meetings at the California DV headquarters, auditing the value of DV's inventory, and reviewing regular financial and other reports from DV employees from approximately 2009 to the present date. The individual defendants are collectively referred to herein as the "Isaias Defendants."

15. Plaintiff is ignorant of the true names and capacities of Defendants sued herein as DOES 1-10, inclusive, and therefore sues these Defendants by such fictitious names. Plaintiff will amend this complaint to allege their true names and capacities when ascertained.

GENERAL ALLEGATIONS

16. DaVinci Biosciences started doing business in Orange County as a biotechnology research and development laboratory in 2008. The company did not sell any products, or earn any revenue, but rather, dedicated its resources to "the discovery and development of cell-based therapeutics … that aid in the treatment of human degenerative disorders." (DV 2012 Business Plan.)

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17. According to the company's website:

> DaVinci Biosciences, LLC is dedicated to improving the quality of life for individuals suffering from degenerative disease and injury. Through responsible research and development, we strive to be innovative leaders in biotechnology and regenerative medicine; renowned worldwide for our scientific and medical achievements and contributions to the health and well-being of communities.

(http://dvbiosciences.com.) In particular, the company is "investigating the use of stem cells to treat patients suffering from" diseases like cardiovascular disease, neurological disease, autoimmune disease, as well as spinal cord injuries, arthritis and other sports injuries. (http://dvbiosciences.com/ clinical-applications /cardiovascular-diseases.).

18. A stem cell is "an unspecialized cell that gives rise to differentiated cells." (Merriam-Webster.com.) There are adult, embryonic and fetal stem cells in humans. Adult stem cells are located in blood, bone marrow and fatty tissues, and generally "act as a repair system for the body, replenishing adult tissues." (https://en.wikipedia.org/wiki/Stem_cell.) Embryonic stem cells are "derived from the inner cell mass of a blastocyst, an early stage embryo" which exists "4-5 days post fertilization." (*Id.*) Fetal stem cells may be located in the "organs of fetuses," "the tissue of the fetus proper" or "extraembryonic membranes." (*Id.*)

19. There is a "right to conduct stem cell research" in the State of California. (Cal. Const. Art. 35 § 5.) The research is believed to hold great promise for the future of medicine. According to DV's 2012 Business Plan, "[s]tem cells or cell therapies have been used for greater than 40 years" for the treatment of disease, and the "cell-based" market related thereto is estimated "to be in the several billion dollar range." (*Id.*)

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A. DaVinci Obtained And Used Aborted Fetus Donations From Planned Parenthood For Their Stem Cell Research

20. DaVinci Biosciences secured its first fetal tissue donations from Planned Parenthood in late 2008 for its research. DV continued to receive fetal tissue donations on a regular basis from Planned Parenthood until 2015. The companies obtained adult tissue samples from donations procured from local hospitals and/or tissue donation centers.

21. Since its founding, the work of DaVinci Biosciences has resulted in two published scientific papers. In its 2014 published study, DaVinci Biosciences reported the results of their initial research on "17- to 18-week-old pre-natal small intestine tissue made available from elective medical abortions," finding "that these cells are a potential in vitro model for drug discovery and development, and possibly in cell transplantation and tissue engineering studies." (Nasrallah et al., *Human Prenatal Small Intestine Cell as a Valuable Source of Stem Cells and Epithelial Cells: Phenotypic and Functional Characterization*, CELL & TISSUE TRANSPLANTATION & THERAPY 2014:6, at pp.1-9.) On July 8, 2015, the company announced that "their paper on 'Stem Cells Targeting Inflammation as Potential Anti-Aging Strategies and Therapies' has been accepted for publication in the peer-reviewed journal Cell & Tissue Transplantation & Therapy." (http:// www. dvbiologics.com/blog/2015/07/published-paper-stem-cells-targeting-inflammation-potential-anti-aging-strategies-therapies/.) The company reports that they are the "first to publish on the process of using stem cells as anti-aging strategies." (*Id.*)

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B. DV Biologics Was Launched In 2009 To Provide A Revenue Stream To The Research And Development Company

22. In early 2009, the Isaias Defendants and DaVinci's then-manager and "CEO" Francisco Silva, among others, collaborated and decided to expand the DaVinci business to include a revenue-driven unit. They decided to start selling products derived from the cells and tissues they were already collecting, processing, storing and using for research purposes. DV Biologics was then incorporated as the sister company to DaVinci Biosciences to generate income using the already established infrastructure of DaVinci Biosciences. DV Biologics began "commercial operations in May 2009 with a minimal product inventory and no marketing or sales." (DV 2012 Business Plan, at p.18.)

23. A few months later, DV launched its first marketing campaign to start producing sales. According to their marketing plan: "The marketing challenge for [2009-2010] will be to introduce our products in a politically conscious way given that the material is both human and in some cases pre-natal derived .... [¶] The challenge will be to form a sales tactic team, infiltrate markets ... to change existing buyer's outlook and purchasing behaviors ... [and to make] human cell-derived products well understood and appear worthy of any additional cost to purchase." (DV Biologics Marketing Plan 2009-2010.)

24. The companies hired an outside marketing consultant to develop marketing materials, including a catalog, to support their sales effort. The 2010 catalog was posted on the company's website in January 2010 and sent to various sales leads in an effort to drive sales.

25. In addition to "post-natal" and diseased tissues and cells, DV advertised the sale of numerous "pre-natal" "products," including fetal "tissue-derived cells" as part of their LIFEbank™ brand. Prenatal tissue and cells from fetal heart, brain, lungs, kidneys, liver, large

intestines, small intestines, skin, skeletal muscle and bones were all offered for sale. They advertised prices in a range as low as $40/vial for "Total RNA" cells from several fetal parts to as high as $1,100/vial for specific cells from fetal brain tissue. Most "products" were priced somewhere in the middle of this range, including, *e.g.*, $300-375/vial for fetal lung cells; $300-450/vial for fetal kidney cells; $500-700/vial for fetal heart cells; and $250-700/vial for fetal liver cells.

26. From one fetus donation, DV created dozens of different types of prenatal "products," and hundreds of individual units of each type for sale. DV was able to do so with a limited number of labor hours (ranging from approximately 2-9 labor hours per "product") and at very minimal costs (usually less than $20/vial). With just a few hours of time, and very little cost, therefore, DV scientists created hundreds of vials of fetal stem cells, which they packaged separately for sale on a per vial basis. DV maintained an inventory of vials "in stock," in one or two refrigerated locations (provided by DaVinci Biosciences) until sold. If they ran out of inventory, they could "easily" make more units from the prior fetus donations or secure a new donation to meet customer demands.

27. In addition to charging a price for each vial/unit of "product," DV also separately charged between $50-75 per purchase order for the "packaging and handling" and "dry ice" used to facilitate the delivery of the products to their customers. An additional "freight" or "shipping charge" was assessed to some customers as well.

28. Between 2009 and 2011, sales revenues nearly tripled as the business started to take shape. "Sales increased 59% in 2011 from 2010" and the DV "product catalog ha[d] grown to greater than 48 pages for 2011-2012." (DV 2012 Business Plan, at p.18.) Defendants sold both adult-derived and fetal-derived tissues and cells to pharmaceutical companies and academic

institutions around the world through a network of distributors. By the end of 2011, DV had 13 worldwide distributors in place and the majority of its revenue was earned from international sales. (*Id.*, at p.2.)

C. Management's 2012-2013 Directive To Push Sales, Beat The Competition, And Increase Revenue Drives Business Forward

29. In late 2011, at the direction of and with the knowledge and participation of the Isaias Defendants, DV executives met to strategize a business plan going forward. According to their 2012 Business Plan developed shortly thereafter, the Defendants' "3 year goals [were] to infiltrate the cell-based market, be a major competitor in the cell-based therapies and tools market for improving health and quality of life, and provide a healthy and conservative balance sheet." (DV 2012 Business Plan, at p.2.) Their "objective" was to develop their "business units into revenue and value generating subsidiaries." (*Id.*, at p.6.)

30. They planned to achieve these goals by "hiring a commercial representative" and/or "a dedicated sales/marketing person," increasing "the amount of marketing" and the "number of distributors throughout the world and tak[ing] advantage of the internet, distributors, newsletters, educational presentations, and direct marketing/sales." (*Id.*, at p.2) They planned "on penetrating the local American market" by securing a United States distributorship agreement. (*Id.*, at p.6.) DV Biologics was required to "market no less than 10 new products yearly." (*Id.*, at p.24.) Management set forth these directives with the "aim to increase sales yearly by no less than 30% each year for the next 3 years ..." (*Id.*, at p.6.)

31. By 2012, DV Biologics had over 500 products in its inventory "with some 13,900 units available," for sale -- an inventory that DV "valued at much greater than $4.4 Million

dollars." (*Id.*, at p.6.) At one point, based on an audit facilitated by the Isaias Defendants, the companies believed the value of the inventory could be as high as $10 million.

32. DV started implementing the directives of the 2012 Business Plan, including retaining additional sales personnel and increasing their marketing efforts by distributing their catalog, newsletters, product brochures and other materials at conferences, via email or by publishing the materials on their website.

33. There was little competition for the sale of many of their prenatal derived "products," so the company began a push to sell their prenatal stem cells as part of their direct marketing efforts. A fall 2012 newsletter, for instance, was distributed that featured small intestine epithelial cells (pD0015-F) for diabetes and weight control research. In late 2012, the DV catalog was also amended to more prominently highlight the distinction between prenatal derived and post-natal derived stem cells for their customers.

34. With a new "Regional Sales Manager" on board in early 2013, the Defendants then implemented a "2013 Sales Launch Plan" to further increase sales. "The primary objective of this plan" was to "help DV Biologics meet or exceed its bottom-line goals & objectives," including a goal to "[g]enerate $550,000 in gross revenue by the end of 2013." (2013 Sales Launch Plan, at p.6.) In addition to improving their "selling techniques," the 2013 Plan called for the hiring of two additional Sales Managers and focusing their efforts on selling "the hottest selling products" (which included, among others, DV's prenatal cardiac cells and small intestine epithelial cells). The 2013 Plan also documented the expectation that the "sales team will go 'above & beyond' what is generally expected," including engaging in "heavy prospecting" to generate "leads" and secure sales. (2013 Sales Launch Plan, at pp.9 & 11.)

35. Beginning in 2012, and continuing for years thereafter under the updated marketing and sales plans, there was a consistent top-down push for staff to sell more "product" and increase revenue. Beginning in 2013, sales staff were also financially incentivized to sell as much as possible by the payment of commissions.

36. From 2012-2015, DV advertised and successfully sold numerous "products," including both "prenatal" and "postnatal" human tissues, cells and systems. A copy of DV's 2013-2014 Catalog is attached hereto as **Exhibit B,** and is fully incorporated herein by reference. "Products" were sold to pharmaceutical companies, academic institutions and distributors both domestically and in countries around the world, including Japan, China, Singapore, Korea, Germany, Switzerland, Spain, Australia, Netherlands, Canada, and the United Kingdom.

37. Although DV did not achieve all of its optimistic revenue goals, their marketing efforts paid off. In both 2013 and 2014, the company grossed in excess of $400,000 in revenue, which was double the gross revenues earned in 2012. In 2015, DV continued its upward momentum and reached its earlier goal to exceed $550,000 in gross revenues. When subtracting the cost of goods sold, DV produced a gross profit on sales every year, except 2012.

38. From 2009-2015, the Defendants also collected approximately $56,678.09 in "packing and handling" fees, which was marked-up approximately 50% over the actual cost of packing and handling. Specifically, DV incurred a total cost of $26,740.92 for packing and handling, and thus profited on the "packing and handling" fees in the amount of approximately $30,000. As a reward to its employees, Defendants also paid commissions on the profits they earned from the packing and handling charges from 2013-2015.

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D. It Is Illegal To Sell Fetal Tissue And Cells For Valuable Consideration Under Both Federal And State Law

39. Under California Health and Safety Code Section 125320:

(a) A person may not knowingly, for valuable consideration, purchase or sell embryonic or cadaveric fetal tissue for research purposes pursuant to this chapter.

(b) For purposes of this section, "valuable consideration" does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of a part.

(c) Embryonic or cadaveric fetal tissue may be donated for research purposes pursuant to this chapter.

(Cal. Health & Safety Code § 125320.)

40. If the "transfer [of fetal tissue] affects interstate commerce" it is also a violation of federal law to "knowingly acquire, receive or otherwise transfer any human fetal tissue for valuable consideration." (42 U.S.C. § 289g-2(a).) As above, "valuable consideration" does not include "reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue." (42 U.S.C. § 289g-2(e)(3).)

41. The term "human fetal tissue" is defined broadly to include any "tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth." (42 U.S.C. § 289g-1(g).) The term "tissue" is also broadly defined generally to "mean[] a human cell, group of cells, including the cornea, sclera, or vitreous humor and other segments of, or the whole eye, bones, skin, arteries, sperm, blood, other fluids, and any other portion of a human body ..." (Cal. Health & Safety Code § 1635(c).)

42. DV knowingly sold hundreds of fetal tissue and stem cell "products" for valuable consideration in violation of these laws.

E. Defendants Set Prices For Fetal "Products" Arbitrarily, Without Any Attempt To Comply With The Law, In An Effort To Maximize Their Profits And Sales

43. In setting the prices for their prenatal "product" sales, DV ignored both federal and state laws that restrict earning "valuable consideration" on such sales entirely. There was no attempt to limit the prices charged on any of their prenatal "product" sales, or related fees, only to "reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue" as the law requires. Indeed, there was no separate accounting for any such allowable charges conducted to support the prices DV charged for prenatal tissues and cells at all.

44. Instead, the majority of sales prices were arbitrarily set initially by the Director of Research and Development for DaVinci Biosciences, Rafael Gonzalez, who set prices based on the "market" value and what other potential "competitors" charged on similar research "tools." In a 2011 email he explained that he relied on the competitors to "do the analysis" on what prices to charge because "[i]f we were to price out each one it would be extremely time consuming."

45. Prices were also intentionally set as high as possible to leave room to offer discounts and negotiate a lower price so as to ensure a profit on sales even with discounts. According to DV's Chief Executive Officer, Francisco Silva's, 2010 directive: when setting prices: "we always negotiate from the top down."

46. Given this price-as-high-as-possible strategy, in an effort to drive sales, DV offered numerous discounts, including distributor discounts (20-30%); first time buyer discounts (10-15%); and bulk purchase discounts (sometimes as high as 50%). The company also regularly offered "sales" pricing promotions, including, for example, a "25% off" summer sale

and "25% off" fall promotion in 2013. Sales staff were given wide flexibility in using discounts in order to close a sale, because they all knew they still ended up "on top."

47. As a result of the pricing structure and the various discounts available, the same "product" was randomly sold to different customers at different prices. The highest prices were typically charged to U.S. customers and educational institutions, while the deepest discounts were offered to international distributors in countries all around the world. Yet, the allowable costs to produce the same "product" did not vary from customer to customer. Thus, only the margin of profit changed, depending on the ultimate price that was negotiated, for each particular sale.

48. Sales personnel knew they were making money on sales, even despite large discounts. For example, in an October 2009 email exchange between DaVinci's Business Development Manager, Janna Lacher, and CEO, Francisco Silva, regarding the pricing of prenatal bone cDNA (pM007-cD), Janna Lacher confirmed her understanding that "it costs us roughly $25 per unit to manufacture and we are selling for $170." She said offering a 30-40% discount price "would leave us with a margin profit of $94-77 per unit" and if they increase the discount to 50%, they "would still have a marginal profit of $60 per unit."

49. Rafael Gonzalez also routinely mentioned how "easily" they could create tissue-derived "products" for sale when discussing pricing. In an email exchange in April 2014 regarding a promotional discount on "chondrocytes and muscle progenitors," Rafael Gonzalez explained: "margins on both products are much higher than 50%. The costs range from $40-50 per vial and we sell them at a 10 fold mar[k] up."

50. In July 2014, DV executives Rafael Gonzalez and Vice President of Sales, Tony Delamaza, specifically discussed the pricing of prenatal renal (kidney) fibroblasts via email.

Rafael Gonzalez explained that they were currently selling the "product" for $350/vial. He said there was no competition for this "product," the cost to make one vial of the postnatal fibroblast was only "in the range of 40 dollars a vial," and thus he recommended they raise the price to $375/vial. Tony Delamaza said he would work on a pricing formula "based on infrastructure, hours spent and intellectual property" but noted: "1000% gross does not seem unreasonable based on infrastructure and lack of competition." Consistent with DV's maximize-the-price culture, Tony Delamaza also said "if the market can handle a higher price then we will go with [that] since we will be giving discounts to the distributors." After this discussion, the 2015 list price for prenatal kidney fibroblasts was set at $450/vial.

51. In 2014 and early 2015, DV's management reviewed the actual cost, including labor, to produce products for purposes of evaluating more specifically the current pricing and their profit margins. The detail was reviewed and edited by Rafael Gonzalez and presented in a report to Tony Delamaza on January 14, 2015 entitled "Pricing per Product FINAL." Only one prenatal "product" type that was analyzed ("RNA products") at or around this time frame appeared to be selling below cost. For the remaining fetal products analyzed, it was clear that there was a substantial profit margin being earned on the prenatal sales, most of which were selling at a profit margin of 70% or more.

F. DV Sold Hundreds Of Units Of Fetal Tissue And Cells For Valuable Consideration

52. From August 2012 to October 2015, it is estimated, using DV's 2015 "Pricing per Product FINAL" analysis (the "2015 Analysis") that DV sold approximately 500 fetal tissue/cell "products" for valuable consideration.

53. For example, one of DV's 2015 "Top Seller" "products" was "Human Cardiomyocytes" cells (pC008-F) derived from fetal heart tissue donations. According to DV's

2015 Analysis, DV can produce 40 vials in a lot, at a cost (including labor) of $25.92 per vial. From 2012-2015, DV sold this "product" at prices of $350/vial (50% off pricing); $490/vial (distributor discount pricing); $560/vial; $595/vial (15% off discount pricing); and $700/vial. Profits on these sales ranged from $324.08 to $674.08 per vial, not including any profits earned on packaging and handling or any other fees charged.

54. One of DV's other 2015 "Top Seller" "products" included "Human Cardiac Progenitor" cells (pC0015-F) derived from fetal heart tissue donations. According to DV's 2015 Analysis, DV can produce 10 vials in a lot, at a cost (including labor) of $62.31 per vial. From 2012-2015, DV sold this "product" at prices of $455/vial; $520/vial; $552.50/vial and $650/vial. Profits on these sales ranged from $392.69 to $587.69 per vial, not including any profits earned on packaging and handling or any other fees charged.

55. Another "Top Seller" included "Human Whole Liver Cells" (pD001-F) derived from fetal liver tissue donations. According to DV's 2015 Analysis, DV can produce 10 vials in a lot, at a cost (including labor) of $18.46 per vial. From 2012-2015, DV sold this product at prices of $125/vial; $175/vial and $200/vial. Profits on these sales ranged from $106.54 to $181.54 per vial, not including any profits earned on packaging and handling or any other fees charged.

56. Similarly, for DV's "Top Seller" "Human CD34 Positive Cells" (pD002-F) derived from fetal liver tissue donations, DV could prepare 10 vials in a lot at a cost (including labor) of $126.17 per vial. DV sold this product at prices of $225/vial and $360 per vial, earning the Defendants a profit between $98.83 and $233.83 per vial on these sales, not including any profits earned on packaging and handling or any other fees charged.

57. DV's "Top Selling" "Stomach cells (uncultured)" (pD005-F), derived from fetal stomach tissue donations, sold for $210, $225 and $240 per vial. Ten vials could be produced in a lot of this product at a cost of $18.46 per vial (including labor). DV earned a profit in a range of $191.54 and $221.54 per vial for these product sales, not including any profits earned on packaging and handling or any other fees charged.

58. "Human Small Intestine Cells (uncultured)" (pD007-F) and "Human Large Intestine Cells (uncultured) (pD008-F), both derived from fetal intestine tissue donations could be produced for sale at a volume of 10 per lot and at a cost (including labor) of $18.46 per vial. These were also "Top Sellers." Prices of $210/vial, $255/vial and $300/vial were charged for these sales, earning DV a profit ranging from $191.54 to $281.54, not including any profits earned on packaging and handling or any other fees charged.

59. Another "Top Seller" included DV's "Human Small Intestine Epithelial Cells" (pD0015-F), also derived from fetal intestine tissue donations. Defendants produced 10 vials in a lot of this product at a cost of $35.91 per vial (including labor). From 2012-2015, DV charged various prices for this "product," including $297.50/vial (50% off discount pricing); $560/vial; $595/vial; $630/vial and $700/vial, therefore profiting in a range of $261.59 to $664.09 per vial on these sales, not including any profits earned on packaging and handling or any other fees charged.

60. With the exception of some of DV's "Total RNA" (-R) fetal tissue derived products, and a handful of free samples that were distributed at a loss, based on its own cost and profit-margin analysis, Defendants profited by large margins on the vast majority of its sales of fetal tissue stem cell "products" from 2009-2015. Defendants knowingly sold each of these "products" with the specific intent to profit on such sales. Each of the 500 prenatal "products"

that were sold for valuable consideration between August 2012 and the present date is a separate violation of both California and federal law for which civil penalties and an injunction preventing any further violations are sought by way of this action.

CAUSES OF ACTION

FIRST CAUSE OF ACTION

(Violation Of Business And Professions Code Section 17200

Against All Defendants)

61. Plaintiff realleges the allegations of paragraphs 1 through 60 above as though fully set forth herein.

62. From 2009-2015, Defendants advertised and sold hundreds of fetal tissue stem cell "products" at prices well in excess of the allowable "reasonable payment for the removal, processing, disposal, preservation, quality control, transplantation or implantation of a part." For every such sale, Defendants sold fetal tissue for valuable consideration in violation of California Health and Safety Code Section 125320 and 42 U.S.C. Section 289g-2.

63. Defendants' conduct was knowing and intentional and in complete disregard of the law. Indeed, rather than attempt to limit their income on sales to allowable amounts, Defendants ignored their legal obligations entirely and affirmatively set forth, at the direction of the Isaias Defendants, a business objective and plan to profit on their sales efforts. From 2009 to 2015, the company acted on these intentions with increasing efforts, resulting in hundreds of profitable sales of fetal tissue and stem cell "products" from 2009-2015. The Isaias Defendants had an obligation and duty to ensure that their companies complied with all such laws, but failed to prevent the violations and knowingly encouraged the unlawful activity to continue. Indeed, throughout, the pressure to make money selling "products" on DV employees was driven by the Isaias Defendants and the other "funding brothers."

64. Defendants' failure to comply with California Health and Safety Code Section 125320 and 42 U.S.C. Section 289g-2 amounts to an unlawful, unfair and fraudulent business practice under California Business and Professions Code Section 17200.

65. The People hereby seek civil penalties of up to $2,500 per violation to the maximum extent permitted by law for Defendants' illegal sales from August 2012 to the present date. It is estimated that DV sold 503 fetal tissue "products" for valuable consideration between August 2012 and the present date, and each such sale is a separate violation.

66. Additionally, the Defendants operated the DV companies without paying all required taxes/fees required for the right to transact business in California, thus resulting in the forfeiture of their rights and powers in the State by the California Franchise Tax Board. (Cal. Rev. & Tax Code §§ 23001 *et seq.*; Cal. Rev. & Tax Code §§ 25101; Cal. Corp. Code §§ 2100 *et seq.*; Cal. Corp. Code §§ 2258-2259.) For every day after November 3, 2014, when the DV Defendants operated their "product" sales business, and for every day after July 28, 2015 when the DV Defendants operated their stem cell research company, without paying all required taxes/fees and thereby reinstating their "powers, rights and privileges" forfeited by the California Franchise Tax Board, Defendants committed further unlawful, unfair and/or fraudulent business practices under California Business and Professions Code Section 17200. The People hereby further seek civil penalties of up to $2,500 per violation for every day the DV Defendants transacted business in the State with a "forfeited" status.

67. The People further hereby seek all appropriate injunctive relief pursuant to Business and Professions Code Section 17203 to prevent any further unlawful activity and any applicable restitution in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants, and each of them, as follows:

1. For civil penalties and restitution in an amount to be determined at trial;
2. An order enjoining Defendants, and each of them, from further violation of California and Federal laws concerning the sale of fetal tissue and cells and from continuing to engage in business in California while their powers rights and privileges remain forfeited;

3. An award of costs and any other applicable fees for prosecuting this action; and

4. Any such other relief as the Court may deem just and proper.

DATED: October 11, 2016

TONY RACKAUCKAS, DISTRICT ATTORNEY
COUNTY OF ORANGE, STATE OF CALIFORNIA

By: _____

KELLY A. ERNBY
Deputy District Attorney